

(e.g., polypropylene screwcapped tubes). If glass vials of spore suspensions are used, they should likewise be placed in polypropylene tubes or other similar containers to simulate microorganisms in typical waste containers.

Prior to testing with the treatment chemical, the unit should be run with tap water. When testing with water or the treatment chemical the test challenge should be placed in the device with the waste and the system started and allowed to operate automatically for one cycle. As the waste and test organisms are being processed, samples of the recirculating chemical and samples of the treated solid material should be collected in clean, sterile containers and processed for surviving organisms.

4.2.4.3 Flow-Through Systems

The initial step in the test method for flow-through mechanical/chemical treatment systems is to identify the passage of liquid effluent through the system. Food dye may be used to help identify the passage of the test organisms through the system and identify sampling times for each sampling site. The first step in the method is the identification of sampling sites.

A bottle of food dye may be added to the device and processed with tap water only flowing through the system (no disinfectant solution; no waste) to identify the sampling window. The sampling window for the test procedure includes the time the dye first appears at the sampling site to the time the dye disappears at that site.

After the sampling window has been identified, a challenge of test organisms should be added to the device and the device should be operated again with tap water and surrogate waste. Liquid effluent samples should be taken during the time period identified as the sampling window along with the solid waste samples. The results are used as a control against which microbial kill from treatment chemical exposure should be measured.

4.2.5 Organism Recovery

The samples collected in the evaluation of chemical or mechanical/chemical treatment systems should be promptly neutralized after collection. An appropriate neutralizing solution should be selected for the specific disinfectant solution. A list of appropriate neutralizing techniques is presented in Table 4.3. It is prudent to consider using two or more means of neutralization. For example, in neutralizing high concentrations of sodium hypochlorite, one may employ dilution (1:10 or greater) in a high protein broth medium that also contains 0.1 percent sodium thiosulfate.

Effective neutralization must be demonstrated before any efficacy testing is undertaken. Neutralization can be evaluated by the addition of increasing amounts of treatment chemical to replicate tubes of the neutralizer broth and then inoculating all samples

with low numbers of a sensitive vegetative organism. As an example, amounts of 0.05, 0.1, 0.3, 0.5, and 1.0 mL of the treatment chemical are added to each of the five tubes containing 10 mL of neutralizer broth. To each tube, including control tubes without treatment chemical, is added a dilution of test cells (e.g., *Staphylococcus* which is sensitive to sodium thiosulfate) that yields between 10 and 40 cells. Appropriate replicate agar plates are also inoculated before and after each tube inoculation to quantify the inoculum. All tubes and plates are then incubated at the appropriate temperature and examined for growth each day for 7 days. Growth in tubes indicates appropriate neutralization at the indicated concentration, while an absence of growth indicates residual chemical exerting a bacteriocidal or bacteriostatic effect, or toxicity of the chemical neutralizer (e.g. sodium thiosulfate).

When testing the actual treatment process, neutralized samples can be mixed and vacuum filtered through a 0.45 µm membrane. The membrane can then be washed in a phosphate buffer to remove the organisms. The resultant organism/buffer solution can be inoculated in duplicate onto an appropriate medium (such as soybean-casein digest agar), streaked for quantitation, sealed in plastic bags, and incubated at 55 °C for at least 48 hours. Alternatively, the membrane may be placed directly onto an appropriate sterile agar surface, inverted, and incubated as described.

4.2.6 Treatment Validation and Routine Testing Frequency

Antimicrobial efficacy of chemical and mechanical/chemical treatment is measured by the calculation of microbial kill per gram of treated waste. The number of organisms determined in the control (tap water) samples is compared with the mean number of organisms recovered from the test samples. The difference between them represents the number of test organisms killed per gram of treated waste solids. This can be represented as follows:

$$K = N_0 - N_2$$

Where: K = Mean number of test organisms killed per gram of treated waste
 N_0 = Mean number of test organisms per gram of waste recovered from the control (tap water) samples.
 N_2 = Mean number of test organisms per gram of waste recovered from the chemical treatment samples.

To validate the treatment process, multiple cycles should be tested along with appropriate control cycles. If results show less than the desired kill in the specified treatment time, then process factors (time, concentration, pH) should be checked and/or modified and the validation testing repeated until results are satisfactory. Once the appropriate operating parameters are established which ensure adequate waste treatment, at least one cycle of the process should be monitored routinely on a bi-weekly basis unless operating parameters change or major repairs are made. Operating parameters (i.e., pH, chemical concentration,

temperature) may be used to monitor daily waste processing for indications of upset conditions. Upset conditions should be recorded and maintenance performed. Testing should then be repeated.

4.2.7 Quality Control Procedures

Quality control procedures presented in Section 1.3.7 should be followed.

5.0 NONIONIZING RADIATION TREATMENT

5.1 GENERAL DESCRIPTION OF TECHNOLOGY

Nonionizing irradiation of medical waste to thermally inactivate microorganisms is an adaptation of an existing technology for a new function. The irradiation may be microwave frequencies or shortwave radiofrequencies.

Two types of microwave treatment systems may be used to treat medical waste. Waste in small clinical or research laboratories may be treated onsite in small, unsophisticated, benchtop microwave ovens. Large hospitals or commercial waste treatment facilities may purchase large special purpose units that shred the waste and then irradiate it with microwaves.

Radiofrequency irradiation is also an adaptation of an existing technology to the treatment of medical waste. Shredded medical waste in insulated containers is exposed to high frequency, short radio waves to heat the waste to the desired temperature. The heated waste is then stored in insulated containers for a specified time after which it may be disposed in a landfill if permitted by local authorities, used for refuse derived fuel, or the plastic portion may be recycled.

There is no evidence at the present time that any intrinsic property of nonionizing irradiation other than thermal heating effect is responsible for microbiological inactivation.

5.1.1 Operational Parameters

5.1.1.1 Frequency/Duration/Direction of Propagation

The factors which affect nonionizing irradiation treatment of medical waste include frequency and wavelength of the irradiation, the duration of the exposure, composition and moisture content of the waste material, and the process temperature of the waste achieved and maintained during treatment.

5.1.1.2 Waste Characteristics/Destruction/Moisture

Refer to Section 1.1 of this document for a general discussion on the description of medical waste and the specific classes that are suitable for each specific medical waste treatment technology.

Microwave treatment units can treat most infectious waste generated at the hospital with the exception of radioactive waste, chemotherapy wastes, human organs or body parts and mixed medical and hazardous wastes.

Ground, shredded , or otherwise destroyed metal items (e.g. hypodermic needles, scalpel blades) are suitable for treatment in microwave treatment systems with the exception of bulk metal materials (metal hip replacements, etc.).

It is advisable that the waste have a significant moisture content to insure effective treatment.

5.1.1.3 Residuals

Nonionizing radiation treatment processes have only solid treated waste residuals. These wastes may be disposed of with municipal wastes where this is permitted. Recycling of portions of treated waste is a possibility for nonionizing radiation treatment residuals, however the waste must be properly segregated into individual materials prior to the treatment process if recycling is to be considered as a viable option. Glass, metal, and properly segregated nonchlorinated plastics may be recycled.

5.1.2 Standard Operating Conditions

5.1.2.1 Microwave Systems

The large microwave units are designed to treat waste at a rate approaching 220 pounds per hour. The waste is placed in a hopper and may be fed by batch mode or continuous mode into a grinding chamber. The grinding process serves a multiple purpose of reducing the volume of waste by approximately 80 percent, rendering the waste unrecognizable, and making the waste more homogeneous. The ground waste is sprayed with steam to increase its moisture content and intensify the heating process.

5.1.2.2 Shortwave Radiofrequency Systems

The shredded waste is compacted into large insulated polyethylene treatment containers. The containers are moved by conveyor out of the processing room and into the dielectric heating area. Low frequency radio waves (11 to 13 MHz) carry the electric energy which are absorbed by the waste materials, heating them uniformly to at least 90 °C as the containers move slowly through the heating area. When the treatment process is complete, the containers are stored for a prescribed period after which the waste material may be disposed of in a sanitary landfill where permitted, recycled as refuse derived fuel, or the plastic portion may be recycled. Because of the size of the equipment, RF treatment currently is limited to commercial waste treatment.

5.2 OPERATION EVALUATION

5.2.1 Test Organism Selection

Non-ionizing radiation as presently utilized cannot achieve Level IV microbial

inactivation. It has, however, the ability to achieve Level III inactivation. Thus, the appropriate indicator organism is *B. subtilis*. Additionally, *B. subtilis* has a thermal death profile very similar to the pathogenic *Clostridium* species which are resistant to thermal inactivation.

5.2.2 Test Organism Procurement

B. subtilis (globigii) ATCC 9372 is the indicator organism of choice. Commercial suspensions may be used to prepare discs or strips containing viable, dried spores. Prepared spore strips of *B. subtilis* (10^4 - 10^8) are available commercially.

5.2.3 Test Organism Quality Control

Commercially prepared spore strips and spore suspensions should be stored according to manufacturers' directions and used before their expiration dates.

5.2.4 Test Challenge Preparation and Loading

A test challenge containing individual *B. subtilis* spore strips of 10^4 or greater should be used. Each challenge of test organisms should be placed in a retrievable, heat and moisture permeable (such as fabric) pouch. The use of spore suspensions in sealed vials is not acceptable, as the treatment will create artificial conditions of temperature and pressure that will not accurately reflect actual waste treatment conditions.

The test pouches should not be ground up with the waste stream. The test pouches should be placed in with the shredded waste and treated in the nonionizing radiation system under normal operating conditions.

5.2.5 Test Load Exposure

5.2.5.1 Microwave System

The test pouches are moved with the moist ground waste by means of a screw conveyor through the microwave treatment chamber over a two hour treatment period. The internal temperature of the treated waste should be maintained at ≥ 90 °C throughout the cycle in order to ensure proper treatment.

The test pouches may be recovered from the treated waste upon discharge. In the laboratory the spore strips are removed and any viable microorganisms are recovered by the method described below.

5.2.5.2 RF Treatment

The test pouches are included in the waste containers before the waste is heated in the RF treatment system. The containers of waste are treated with the RF irradiation and then allowed to stand for a period of time after which the test pouches are removed from the waste and any viable microorganisms are recovered according to the method described below.

5.2.6 Organism Recovery

Recovery of test organisms requires aseptic inoculation of test discs or strips into 5.0 mL soybean-casein digest broth medium (or equivalent) followed by incubation for at least 72 hours. Additional samples are processed as viability, media, and incubation controls. All *B. subtilis* samples are incubated at 32 °C.

At the end of the required incubation time, media that were inoculated with the test organisms are examined for turbidity as an indicator of growth. If growth is noted, it is a preliminary indication that some indicator spores survived the treatment process. To confirm the identity of the organisms present in the media demonstrating growth, all positive test cultures including control cultures are subcultured onto soybean-casein digest agar plates (or equivalent) and incubated at the appropriate temperature (32 °C) for at least 24 hours. The colonies are then identified to determine if the growth is the indicator organism. Level III microbial inactivation is indicated by the inactivation of a minimum of 10^4 *B. subtilis* spores.

5.2.7 Treatment Validation and Routine Testing

To validate the treatment process, duplicate trials should be tested on each of three different days, with no surviving *B. subtilis* spores. If results show surviving spores, then the treatment process parameters (frequency, exposure time, water content, waste temperature) should be checked and/or modified and the validation testing repeated until results are satisfactory. Once the appropriate operating parameters are established that insure adequate waste treatment, at least one cycle of the process should be monitored routinely on a bi-weekly basis unless the operational parameters are changed or major repairs of the equipment are performed. The microwave and radiofrequency systems have visual readouts of the treatment process. The radiofrequency system also monitors the temperature in the waste load. These can be used to monitor the daily waste processing for upset conditions.

5.2.8 Quality Control Procedures

Quality control procedures presented in Section 1.3.7 should be followed.

6.0 WORKER HEALTH AND SAFETY

6.1 OCCUPATIONAL CONCERNS OF MEDICAL WASTE TREATMENT

Those with exposure to medical waste are subject to 29 CFR Part 1910.1030, Occupational Exposure to Bloodborne Pathogens; Final Rule, Occupational Safety and Health Administration, 1991.

6.1.1 Biological Hazards

Personnel involved in the treatment of medical waste may be exposed to infectious agents through several routes including skin penetration, skin contact, or by the aerogenic route. Exposure routes will vary with the type of treatment used. Medical waste may contain a variety of human pathogens including bacteria, fungi, viruses, and parasitic organisms as well as microbial toxins.

6.1.2 Physical and Chemical Hazards

Needle sticks, cuts, falls, strains, sprains, burns, and eye, back, electrical, mechanical, and chemical injuries are additional potential consequences of medical waste treatment. Additional hazards include radioactive, hazardous, and cytotoxic waste exposures.

6.1.3 Health Promotion and Protection

The promotion and protection of the health of medical waste treatment workers and the control of biological, physical, and chemical hazards to which they are exposed can be achieved through proper training, supervision, and health surveillance. Training employees in the proper operation of treatment equipment includes the use of any personal protective equipment needed. Health surveillance may also include proper immunization of employees who are potentially exposed to untreated medical waste

6.1.4 Onsite Medical Waste Treatment Technologies

6.1.4.1 Incineration

Incinerator operations can present other occupational hazards in addition to potential infection or burns. Toxic organic compounds or metals on respirable particles in ash may pose an inhalation risk. Additional hazards are also faced during maintenance and operation of air pollution control devices. Caustic burns can result from exposure to wet scrubber caustic liquid. Hypoventilation can be a risk during maintenance of fabric filters due to low oxygen in combustion gas. Injuries can also occur from contact with some incinerator components such as moving belts, hydraulic cylinders, ram feeders and ash conveyors.

Finally, heat stress is associated with incinerator inspection and repair because of the hot humid conditions and length of time required (EPA, 1989).

Potential infection from pathogens in medical waste and fires or explosions in the incinerator are the two greatest risks faced by incinerator operators. Exposure to infectious organisms is most likely to occur through handling of needles and other sharps prior to treatment. Fires could occur during charging of waste to the incinerator, especially if highly flammable materials are ignited by the incinerator burner.

6.1.4.2 Steam Autoclaving

All steam autoclaves require manual waste handling at some point in the loading process. The chambers of standard laboratory and hospital autoclaves, as well as commercial onsite steam autoclave treatment systems, are manually loaded with bags and containers of medical waste. In many instances the treatment operator will push the waste into the chamber with bare hands. This places the operator at risk of exposure through skin penetration from inappropriately shielded or contained sharps as well as possible exposure through aerosolization if the waste bags rupture. Waste may also contaminate the operator's hands, which may then transmit disease agents via contact with mucous membranes. Unprotected hands may also result in burns from contact with hot autoclave walls and doors.

6.1.4.3 Chemical/Mechanical Treatment

Individuals using chemical microbial inactivation or a small mechanical/chemical treatment device can place waste directly into the treatment system at the point of generation thus minimizing handling and exposure. Large onsite mechanical/chemical systems, however, require transport and loading of large quantities and varieties of medical waste items. The risk of exposure from skin penetration or contact with infectious agents is present. Aerogenic exposure may also occur from broken waste bags or from a contaminated conveyor belt or hopper that provides entry of the waste into the system. Workers risk exposure to treatment chemicals, either by contact or inhalation routes. It is imperative that such treatment systems be effectively decontaminated prior to disassembly for maintenance or repairs.

6.1.4.4 Microwave Irradiation

Although currently available microwave treatment does not require manual waste loading, potential worker exposure can occur through the aerogenic and dermal contact routes when access to the shredder is required during the treatment process. Access involves opening a small port in the side of the unit where the shredder is located and where the untreated waste is prepared for microwave exposure. Burns may occur as a treatment operator works with or near components associated with the steam injector, and microwave exposure may occur if leakage from the system is not monitored. It is imperative that such treatment systems be effectively decontaminated prior to disassembly for maintenance or repairs.

6.1.5 Offsite Medical Waste Treatment Technologies

6.1.5.1 Incineration

The hazards associated with the offsite treatment of medical waste by incineration are the same as have been described for onsite treatment.

6.1.5.2 Steam Autoclaving

Potential exposure by the aerogenic and dermal contact routes may occur as workers load up to 1,000 pounds of medical waste into treatment bins. The potential for injuries to occur from heat, falls, and mechanical equipment is also great.

6.1.5.3 Non-ionizing Irradiation

The loading of untreated and shredded medical waste into containers for radiofrequency treatment is manually controlled by a worker. The operator loading the shredded medical waste dons full protective clothing and appropriate respirator, thus minimizing aerogenic or contact exposure. Exposure to the radiofrequency waves may be precluded by adhering to operational precautions during treatment and heeding warning devices. The potential exists for injuries due to lifting, falling, and exposure to mechanical equipment.

6.2 WORKER TRAINING

6.2.1 Safety

Medical waste treatment operators should be provided with information and training on the process and mechanical operation of the treatment system they are using. They should have a full understanding of all operational controls and know what to do and/or whom to contact in response to a system failure or other emergency.

Appropriate safety training as required by Federal and State Occupational Safety and Health Administration (OSHA) regulations must be provided. Steam autoclaving, microwave and radiofrequency treatment system operators should be trained to prevent burns and eye and back injuries. Chemical treatment system operators should be provided with appropriate Material Safety Data Sheets (MSDS) and be trained to prevent chemical exposure, hearing loss, and mechanical and back injuries. Incinerator operators should be trained in appropriate waste feed handling, incinerator operation, and ash removal. All treatment technologies should provide a working environment designed to prevent slips and falls, and specific training on the use of personal protective equipment should be conducted.